REMARKS/ARGUMENTS

Reconsideration of this application, as amended, is respectfully requested.

Claims 1-10 are pending in the present application.

Claims 1-10 have been rejected.

In the present response, in order to expedite prosecution of the present application, claim 1 has been amended to include the language of dependent claims 2-4; and claims 2-4 have been cancelled. Dependent claim 5 has been amended to be dependent on claim 1. Claim 7 has been made independent by including the language of claim 1. Likewise, claim 9 has been made independent by including the language of claim 1. Support for these amendments is in the specification, as filed (e.g, at page 4, line 24, to page 5, line 5), and no new matter is added to the specification with these amendments. Therefore, their entry is respectfully requested. Also, the Examiner is authorized to charge Applicant's deposit account for any additional fees that may be due, resulting from Applicant's making claims 7 and 9 independent.

The Examiner noted that Applicant's arguments with respect to claims 1-10 have been considered but are not persuasive for the reasons set forth in the office action mailed October 21, 2003.

CLAIM REJECTIONS – 35 USC § 112, FIRST PARAGRAPH

Claims 1-10 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the limitation "consisting essentially of" lacks antecedence in the specification. According to the Examiner, Applicant's disclosure fails to teach a method comprising solely the step of administering cholesterol lowering agents. The Examiner concludes that for purposes of examination "consisting essentially of" is assumed to include some dietary modifications.

The term "consisting essentially of" is a well-recognized transitional phrase used in claim language, which limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention (see MPEP 2111.03). Furthermore, this phrase does not need to appear explicitly for it to be supported by the present specification. The Federal Circuit and its predecessor have repeatedly held that "claimed subject matter need not be described in

haec verba in the specification in order for that specification to satisfy the written description requirement," e.g., In re Wright, 866 F2d. 422, 9 USPQ 2d 1649, 1651 (Fed. Cir. 1989); and In re Smith, 481 F.2d 910, 914, 178 USPQ 620 (CCPA 1973). The court will look to the "essence of the original disclosure" in determining compliance with the written description requirement, see In re Wright at page 1651.

Applicant would point out that claims 1, 5, 7 and 9 have been amended, as noted above, and that the language of claim 1, as amended, is supported by the present specification as filed, including page 4, line 24, to page 5, line 5; and Example 1, page 7, line 11, to page 25, line 24. Therefore, Applicant respectfully requests that this rejection of claims 1-10, as amended, under 35 USC § 112, first paragraph, be withdrawn.

CLAIM REJECTIONS – 35 USC §102

Claims 1-3 are rejected under 35 USC § 102(e) as being anticipated by Seed et al. (U.S. Patent No. 5,861,399). The Examiner refers to line 62 of col. 2 through line 20 of col. 3 of the Seed reference.

As noted above, in order to expedite prosecution of the present application, claim 1 has been amended to include the language of dependent claims 2-4. Therefore, claim 1 is now directed to the use of atorvastatin, or a pharmaceutically acceptable salt thereof, to prevent or delay catheter-based revascularization in patients suffering from coronary artery disease. The Seed reference does not disclose the use of atorvastatin or a pharmaceutically acceptable salt in its methods or compositions.

As Applicant has noted in previous responses, a claim is anticipated only if each and every element as set forth in the claim is found in the prior art reference (see, Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). The Seed reference does not disclose each and every element of claim 1, as amended; therefore, Applicant respectfully requests that this rejection under 35 USC § 102(e) be withdrawn. Furthermore, for the reasons given below, Applicant would assert that the Seed reference does not teach or suggest the methods, as claimed in the present invention, under 35 USC § 103.

CLAIM REJECTIONS – 35 USC §103

Claims 1-4 and 9-10 are rejected under 35 USC § 103(a) as being unpatentable over

Whitney et al. (U.S. Patent No. 6,180,660) in view of Jeevanandam et al. (U.S. Patent No. 5,957,916). The Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Whitney et al. by preventing a catheter based revascularization procedure as taught by Jeevanandam et al.

The present claims are directed toward a method for preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease and in need of such treatment comprising administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol. As Applicant has noted previously, Whitney does not teach or suggest preventing or delaying revascularization in patients suffering from coronary artery disease. The disclosure of Whitney is around the treatment of individuals without coronary artery disease. The clinical trial that is the basis for the Whitney disclosure, the AFCAPS/TexCAPS trial, is limited to "a cohort without clinical evidence of atherosclerotic cardiovascular disease" (see col. 5, line 62, to col. 6, line 5). Entrance inclusion criteria included that the patient's LDL level be 130-190 mg/dl (see col. 5, lines 44-45). Indeed, during the trial, patients with LDL levels greater than 195 mg/dl were withdrawn from the trial (see col. 7, lines 32-35). Col 6, lines 33-36 of Whitney reads "Excluded [from the trial] for clinical evidence of atherosclerotic cardiovascular disease were men and women who had: prior history of myocardial infarction; . . . " Therefore, the results of Whitney would not have conveyed to one of skill in the art that treatment with a cholesterol lowering agent could prevent or delay revascularization in patients suffering from coronary artery disease, as is claimed in the present invention – that patient population was simply not studied in Whitney.

Furthermore, the Jeevanandam reference, which is from a non-analogous art area, does not make up for the deficiencies of the Whitney disclosure. As Applicant has noted in previous responses, while Jeevanandam does describe methods of catheter-based revascularization for patients unable to undergo bypass surgery, it does not teach or suggest anything in relation to how or if one could avoid the need for revascularization using drug therapy, as is claimed in the present invention.

It is in Applicant's disclosure that support is found for the prevention or delay of catheter-based revascularization in patients suffering from coronary artery disease by administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol. Applicant is the first to show that high doses of a cholesterol

lowering drug, such as atorvastatin, reduce the incidence of an adverse cardiac event from 21% to 13%, thereby, decreasing the need for revascularization (see present specification at page 25, lines 5-24).

Because the Whitney and Jeevanandam references fail to teach or suggest all of the claimed elements, fail to provide motivation to combine the references and fail to provide a reasonable expectation of success, Applicant respectfully requests that this rejection of claims 1-4 and 9-10, as amended, under 35 USC § 103 be withdrawn.

Claims 1-6 are rejected under 35 USC § 103(a) as being unpatentable over Bocan (WO 97/16184) in view of Jeevanandam et al. (U.S. Patent No. 5,957,916). The Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Bocan by preventing a catheter based revascularization procedure as taught by Jeevanandam et al.

The Bocan reference teaches the lowering of LDL by a combination of an acyl-coenzyme A: cholesterol acyltransferase (ACAT) inhibitor and an HMG-CoA reductase inhibitor. Nowhere in Bocan is it disclosed that catheter-based revascularization in patients suffering from coronary artery disease can be prevented or delayed by administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol, as is claimed in the present invention. Bocan only discloses that a combination of ACAT inhibitors and HMG-CoA reductase inhibitors reduces apo B-containing lipoprotein levels to a greater extent that either inhibitor alone, that a normalization of plasma lipoprotein profile is achieved, and that the histolic character of atheosclerotic lesions is less complicated when the combination is used.

Furthermore, for the reasons given above, the Jeevanandam reference, which is from a non-analogous art area, does not make up for the deficiencies of the disclosure of Bocan, which is directed to combination therapy. Therefore, because the Bocan and Jeevanandam references fail to teach or suggest all of the claimed elements, fail to provide motivation to combine the references and fail to provide a reasonable expectation of success, Applicant respectfully requests that this rejection of claims 1-6, as amended, under 35 USC § 103(a) be withdrawn.

Claims 1, 7 and 8 are rejected under 35 USC § 103(a) as being unpatentable over Bisgaier et al. (U.S. Patent No. 5,648,387) in view of Jeevanandam et al. (U.S. Patent No. 5,957,916). The Examiner alleges that it would have been obvious to one of ordinary skill in

the art at the time of the invention to modify the method disclosed by Bisgaier et al. by preventing a catheter based revascularization procedure as taught by Jeevanandam et al.

Bisgaier teaches the utility of dialkyl ethers in lowering Lp(a), triglycerides and LDL-cholesterol and in raising HDL-cholesterol. However, Bisgaier does not teach or suggest administration of an amount of a cholesterol-lowering agent effective to cause an aggressive lowering of LDL cholesterol. Nor does Bisgaier teach or suggest a method for preventing or delaying revascularization. While Bisgaier does, in passing, disclose a method of treating vascular diseases such as restenosis (see col. 2, lines 49-51), Applicant would point out that treating restenosis is different than preventing or delaying revascularization where there has not been an initial surgical procedure, as explained in Applicant's previous responses. Thus, Bisgaier does not disclose or suggest a method of preventing or delaying catheter-based revascularization, as is claimed in the present invention.

Furthermore, for the reasons given above, the Jeevanandam reference, which is from a non-analogous art area, does not make up for the deficiencies of the Bisgaier disclosure. Therefore, because the Bisgaier and Jeevanandam references fail to teach or suggest all of the claimed elements, fail to provide motivation to combine the references and fail to provide a reasonable expectation of success, Applicant respectfully requests that this rejection of claims 1, 7 and 8, as amended, under 35 USC § 103(a) be withdrawn.

One of skill in the art would not have reasonably expected the above-cited reference methods to succeed without referring to data, such as the data provided by the disclosure in Applicant's specification. It is in Applicant's disclosure that the support for prevention or delay of catheter-based revascularization in patients suffering from coronary artery disease is found. As noted above, Applicant is the first to show that high doses of a cholesterol lowering drug, such as atorvastatin, reduce the incidence of an adverse cardiac event from 21% to 13%, thereby decreasing the need for revascularization (see present specification at page 25, lines 5-24). As the Examiner is well aware, to establish a *prima facie* case of obviousness, the reasonable expectation of success must be found in the prior art references, and not in Applicant's own disclosure.

Therefore, Applicants submit that the claims, as currently amended, are patentable over the above-cited references, either singly or in combination, and respectfully request that all rejections of the claims under 35 USC § 103 be withdrawn.

On the basis of the above amendments and remarks, reconsideration of this application, as amended, and its early allowance, are respectfully requested.

Respectfully submitted,

Date: May 24, 2004

Martha A. Gammill
Attorney for Applicants
Reg. No. 31,820
Pfizer Inc.
Patent Department
2800 Plymouth Road
Ann Arbor, MI 48105
Tel. (734) 622-5940
Fax (734) 622-1553

Attachments:
Petition for Extension of Time Form
Associate Power of Attorney Form
Fee Transmittal
Request for Continued Examination